IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

BEVERLY KIVEL,

Plaintiff,

v. CIVIL ACTION NO. 2:12-cv-0591

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Defendants' Motion for Summary Judgment)

Pending before the court is the defendants' Motion for Summary Judgment [ECF No. 67]. As set forth below, the defendants' Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to the court by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 28,000 of which are in the Ethicon, Inc. and Johnson & Johnson, Inc. ("Ethicon") MDL, MDL 2327. In an effort to efficiently and effectively manage this massive MDL, the court decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled

on all summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, the court ordered the plaintiffs and defendants to submit a joint list of 200 of the oldest cases in the Ethicon MDL that name only Ethicon, Inc., Ethicon, LLC, and/or Johnson & Johnson. These cases became part of a "wave" of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order No. 193, *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002327, Aug. 19, 2015, *available at http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html*. I completed this selection process four times and selected the plaintiff's case as a Wave 1 case.

On January 5, 2005, Ms. Kivel was surgically implanted with Gynemesh/Gynemesh PS ("PS"), a product manufactured by Ethicon. Am. Short Form Compl. ¶¶ 9–10 [ECF No. 22]. Ms. Kivel's surgery occurred at Regions Hospital in St. Paul, Minnesota. *Id.* ¶ 11. Ms. Kivel claims that as a result of implantation of the PS, she has experienced multiple complications. She brings the following claims against Ethicon: negligence, strict liability manufacturing defect, strict liability failure to warn, strict liability defective product, strict liability design defect, common law fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, breach of express and implied warranties, violation of consumer protection laws, gross negligence, unjust enrichment, punitive damages, and discovery rule and tolling. *Id.* ¶ 13.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict" in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731

F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, the court generally refers to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010). The plaintiff in this case originally filed her complaint in the United States District Court for the District of Minnesota. (*See* Compl. & Jury Demand 1 [ECF No. 1]). Accordingly, I must apply Minnesota's choice-

of-law rules.

The parties agree, as does the court, that these principles compel application of Minnesota law to the plaintiff's claims. Minnesota focuses on two factors in resolving choice-of-law issues: (1) the maintenance of interstate order and (2) the advancement of the forum state's interest. *See In re Baycol Prods. Litig.*, 218 F.R.D. 197, 207 (D. Minn. 2003) (stating that only two factors in Minnesota's usual five-factor test apply to the resolution of choice-of-law issues arising under tort law) (citing *Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 604 N.W.2d 91, 94–96 (Minn. 2000)).

With respect to the first factor, the court should look to the state with "the most significant contacts with the facts relevant to the litigation." *Id.* Here, that state is Minnesota, where the plaintiff resides, underwent implantation surgery, and received follow-up medical care. (*See* Am. Short Form Compl. ¶ 4, ¶ 11 [ECF No. 26]; Pl.'s Resp. in Opp. To Def.'s Mot. For Summ. J. 1–5 [ECF No. 79]). The second factor, which requires the court to consider "the state law in which the plaintiff lives and in which the injury occurred," also weighs in favor of applying Minnesota law. *See, e.g., In re Baycol*, 218 F.R.D. at 207 ("[A]s the injury occurred in the state of plaintiff's residence, the substantive law of the state of plaintiff's residence should be applied to their claims."); *Foster v. St. Jude Med., Inc.*, 229 F.R.D. 599, 605 (D. Minn. 2005) ("[P]roper consideration of Minnesota's choice-of-law factors reveals that the law of the state where the [d]evice was implanted would apply to Plaintiffs' [products liability] claims.").

Having considered both factors in Minnesota's choice-of-law test, I find that Minnesota law governs the plaintiff's substantive claims in this case. I now turn to the merits of the pending motions.

III. Analysis

Ethicon argues it is entitled to summary judgment because the plaintiff's legal theories are without evidentiary or legal support. In her Response [ECF No. 77], the plaintiff withdraws several of the Counts listed in her Amended Short Form Complaint: Count II, strict liability manufacturing defect; Count IV, strict liability defective product; Count VI, Fraud; Count VII, fraudulent concealment; Count VIII, constructive fraud; Count IX, negligent misrepresentation; Count X, negligent infliction of emotional distress; Count XI, breach of express warranty; Count XII breach of implied warranty; Count XIII, violation of consumer protection laws; Count XIV, gross negligence; and Count XV, unjust enrichment. Accordingly, Ethicon's Motion with regard to these claims is **GRANTED**. Below, the court applies the summary judgment standard to each remaining claim.

A. Statute of Limitations

As a threshold matter, Ethicon argues that the plaintiff's remaining strict liability claims are barred by a four-year statute of limitations. Minn. Stat. Ann. § 541.05, subd. 2. This statute incorporates a discovery rule which provides that "a cause of action does not accrue until two elements are satisfied: '(1) a cognizable physical manifestation of the disease or injury, and (2) evidence of a causal connection

between the injury or disease and the defendant's product, act, or omission.'" *Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 984 (D. Minn. 2013) (quoting *Hildebrandt v. Allied Corp.*, 839 F.2d 396, 398 (8th Cir. 1987)).

Minnesota's discovery rule requires that the plaintiff suffer only "some damage" to trigger the statutory clock. *Narum v. Eli Lilly and Co.*, 914 F. Supp. 317, 320 (D. Minn. 1996). The discovery rule is not, however, "intended to provoke the premature commencement of claims for temporary sickness or discomfort. Rather, the plaintiffs are entitled to wait until the cause has been rationally identified." *Hildebrandt,* 839 F.2d at 399 (applying Minnesota law). Ultimately, a plaintiff's claim accrues when she "is aware of both her injury and the likely cause of her injury," and "waiting for a more serious injury to develop from the same cause" will not delay the accrual date. *Klempka v. G.D. Searle & Co.*, 963 F.2d 168, 170 (8th Cir. 1992).

Ethicon asserts that Ms. Kivel identified the PS as the cause of her injury when she reported suffering from pain to Dr. Sharpe, her implanting physician, on November 16, 2007, approximately two years after the PS was implanted. Mem. in Sup. 6 [ECF No. 68]. Ms. Kivel testified that she did not attribute her symptoms to the PS—and, in turn, to Ethicon—until she saw a television advertisement referring to "the defectiveness of mesh" in 2011. Kivel Dep. 32:21–33:6, Nov. 4, 2015 [ECF No. 77-2]. Plaintiff also argues that the earliest possible date Ms. Kivel could have known that the PS was causing her problems was when the FDA issued a Public Health Notification on October 20, 2008. Resp. 6 [ECF No. 77]. The plaintiff asserts that Dr.

Sharpe had given Ms. Kivel no reason to believe that her injuries were caused by the PS product before that time. *Id.* at 7. In fact, Dr. Sharpe testified that, at the time of Ms. Kivel's November 2007 visit, Dr. Sharpe primarily attributed the plaintiff's pain to scarring and contracting of an incision from the implantation surgery and "the physical findings related to the graft itself were absolutely unremarkable." Sharpe Dep. 110:5–111:7, 113:19–21, Dec. 16, 2015 [ECF No. 77-2].

In light of the evidence proffered by Ms. Kivel and the defendants, there is a genuine dispute of material fact as to when Ms. Kivel was aware of the causal connection between the PS and her injuries. *See Hildebrandt*, 839 F.2d at 398 (explaining that the statute of limitations begins to run with "(1) a cognizable physical manifestation of the disease or injury, and (2) evidence of a causal connection between the injury or disease and the defendant's product, act, or omission"). Accordingly, Ethicon's Motion for Summary Judgment with regard to statute of limitations is **DENIED**.

B. Strict Liability

Minnesota has adopted the doctrine of strict liability for defective products set forth in section 402A of the Restatement (Second) of Torts. *See Lee v. Crookston Coca-Cola Bottling Co.*, 188 N.W.2d 426, 432 (Minn. 1971); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1146 (D. Minn. 2011).

Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to

> liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A (Am. Law Inst. 1965). Under this doctrine, Minnesota "imposes liability, without proof of negligence or privity of contract, upon a manufacturer or seller for injury caused by a dangerously defective product." *Lee*, 188 N.W.2d at 432.

1. Design Defect

In Minnesota, a plaintiff bringing a design defect claim under strict liability must prove, through an objective "reasonable care balancing test," that a defendant failed to execute reasonable care. *Bilotta v. Kelley Co., Inc.*, 346 N.W. 2d 616, 621–22 (Minn. 1984). This balancing test requires "a balancing of the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm." *Id.* at 621 (quoting *Holm v. Sponco*, 324 N.W. 2d 207, 212 (Minn. 1982)). On one side of the balancing test, a court must consider "the relative costs and benefits of an allegedly defective design." *Kapps*, 813 F. Supp. 2d at 1161. On the other side, a court will weigh "the relative costs and benefits of one of

two different things: either (1) a proposed alternative design, or (2) the removal of the challenged product from the market." *Id.* "In almost every design defect case, a plaintiff will demonstrate a safer design as part of establishing liability." *Block v. Toyota Motor Corp.*, 5 F. Supp. 3d 1047, 1067 (D. Minn. 2014). Indeed, "[o]nly in rare cases," will a plaintiff prevail in her claim by arguing that a product "should be removed from the market rather than be redesigned." *Block*, 5 F. Supp. 3d at 1067; *Kallio v. Ford Motor Co.*, 407 N.W. 2d 92, 96–7 (Minn. 1987).

Ethicon's Motion seeks summary judgment on the plaintiff's design defect claims on the basis that the plaintiff has neither shown the existence of a safer alternative design nor presented evidence to show that the PS was so dangerous that it should have been removed from the market. The plaintiff, however, has proffered evidence of an alternative design and has produced evidence that the purported safer alternative designs would have reduced Ms. Kivel's injuries, would not have affected the product's utility, and would have been economically and technologically feasible. Accordingly, the court finds that there remains a genuine dispute of material fact regarding the existence of a safer alternative design under Minnesota law. Ethicon's Motion on the plaintiff's strict liability design defect claim is **DENIED**.

2. Failure to Warn

Minnesota, like many jurisdictions, has adopted the learned intermediary doctrine, which applies to strict liability claims. *Kapps*, 813 F. Supp. 2d at 1152 (citing *Mulder v. Parke Davis & Co.*, 181 N.W. 2d 882, 885 n.1 (Minn. 1970)). Under this

doctrine, "a maker of drugs or medical devices has a duty to warn only doctors (the learned intermediaries)—and not patients—about the dangers associated with a drug or medical device." *Id.* Therefore, a strict liability claim fails when a medical-device manufacturer provides an adequate warning to a plaintiff's doctor. *Id.* A strict liability claim will also fail if a plaintiff fails to prove that the allegedly inadequate warning caused the plaintiff's injures; the causal chain is broken when a doctor (1) is fully aware of the information that a medical-device manufacturer "wrongly failed to provide" and (2) the doctor "would have taken the same action even if the defendant had included that information in the warning." *Id.* (citing *Cornfeldt v. Tongen*, 262 N.W. 2d 684, 698 (Minn. 1977)). Both the adequacy of the warning and causation are questions of fact to be resolved by the jury. *Balder v. Haley*, 399 N.W. 2d 77, 81 (Minn. 1987).

Here, the plaintiff has offered evidence from which a reasonable juror could return a verdict in her favor, and genuine disputes of material fact exist with regard to (1) whether Ethicon's warning was adequate, and (2) whether the alleged inadequate warning proximately caused the alleged harm to Ms. Kivel. Therefore, Ethicon's Motion for Summary Judgment on Ms. Kivel's strict liability for failure to warn claim is **DENIED**.

C. Negligence

Under Minnesota law, "[t]he distinction between strict liability and negligence in design-defect and failure-to-warn cases is that in strict liability, knowledge of the

condition of the product and the risks involved in that condition will be imputed to the manufacturer, whereas in negligence these elements must be proven. *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 622 (Minn. 1984). Ultimately, however, "with respect to failure-to-warn and design-defect claims, the theories of negligence and strict liability are effectively merged into a single theory of products liability" once it goes to a jury. *Kapps*, 813 F. Supp. 2d at 1146 (citing *Bilotta*, 346 N.W.2d at 623).

Here, Ethicon argues only that summary judgment is proper on these claims because the claims are duplicative of the strict liability claims. As discussed above, the plaintiff has proffered sufficient evidence regarding the alleged existence of a safer alternative design and lack of an adequate warning. Additionally, the plaintiff's negligence claims are not contingent on the outcome of her strict liability claims; they are independent claims and not merged into a single theory until they go to the jury. Ethicon's Motion regarding the plaintiff's negligence claims is **DENIED**.

D. Punitive Damages and Discovery Rule & Tolling

Ethicon asserts that its Motion challenges all of the plaintiff's claims, which include punitive damages and discovery rule and tolling. Mot. Summ. J., at 1. Ethicon, however, does not present any arguments regarding these claims. The court will not make arguments for Ethicon. Accordingly, Ethicon's Motion regarding the plaintiff's claims for punitive damages and discovery rule and tolling is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that Ethicon's Motion for Summary Judgment [ECF No. 67] is **GRANTED in part** and **DENIED in part**. As the plaintiff has conceded these claims, Ethicon's Motion is **GRANTED** with regard to the plaintiff's claims for: Count II, strict liability manufacturing defect; Count IV, strict liability defective product; Count VI, Fraud; Count VII, fraudulent concealment; Count VIII, constructive fraud; Count IX, negligent misrepresentation; Count X, negligent infliction of emotional distress; Count XI, breach of express warranty; Count XII breach of implied warranty; Count XIII, violation of consumer protection laws; Count XIV, gross negligence; and Count XV, unjust enrichment. Ethicon's Motion regarding the plaintiff's strict liability design defect, strict liability failure to warn and negligence claims is **DENIED**.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 19, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE